

REMARKS

Claims 80, 100, 232, and 241-255 are pending. Claims 232, 243-246, and 248-250 have been amended. No claims have been added or canceled. As such, Claims 80, 100, 232, and 241-255 are pending, of which claims 232 and 241-255 are under consideration. Support for the present amendment may be founded in the specification and original claims, e.g., by way of the positive recitation of alternative elements of the original claimed embodiments (see MPEP § 2173.05(i)). No new matter enters by way of the present amendment. As such, entry of the amendment and consideration of the claims as amended is respectfully requested.

I. Restriction Requirement

Applications acknowledge with traverse the finality of the restriction/election requirement, and confirm that Claims 232 and 241-255 at least partially read on the elected species. Applicants also expressly reserve the right to rejoin non-elected species upon allowance of claims to the presently elected species, as well as any non-elected methods as appropriate upon allowance of the elected product claims pursuant to MPEP 821.04.

II. Claim Rejections under 35 U.S.C. § 102

A. Rejection over Ryono

Claims 232 and 241-255 stand rejected under 35 U.S.C. § 102(a) or (e) as being allegedly anticipated by Ryono *et al.*, US 2005/004184 A1 (see CAS: 141:395288) (hereinafter “Ryono”). This rejection is respectfully traversed for at least the reasons which follow.

It is well established that to anticipate a claim, a reference must disclose every element of the claim. *Verdegaal Bros. v. Union Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicants submit that cited prior art fails to disclose each and every element of the present claims, and therefore does not anticipate the claimed invention.

In rejecting the claims at issue, the Examiner asserts that Ryono disclose a compound that “clearly anticipate the instant compounds of formula (VIII)” *Office Action* mailed July 28, 2009 at page 5. While not agreeing with the rejection, the claims have been amended such that the compounds disclosed by Ryono clearly do not overlap with the claimed compounds.

Specifically, the compounds disclosed in Ryono do not overlap with the presently claimed compounds in at least substituent R³. As such, whatever else Ryono may disclose, Ryono does not teach or suggest any structure, formulae or embodied compounds which overlap with the specific definitions recited in the claims for R³. Ryono therefore does not teach each and every element of the present claims. For at least this reason, withdrawal of this rejection is therefore respectfully requested.

B. Rejection over Ibrahini, Hopper, Li, and Gibbs

Claims 92, 130, 163-204 are stated to be rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by (1) Ibrahini et al., CAS 133:14000 (hereinafter “Ibrahini”); (2) Hopper et al., CAS 130:332269 (hereinafter “Hopper”); (3) Li et al, US Pat 6,465,687 (hereinafter “Li”); or (4) Gibbs et al., US Pat 5,519,163 (hereinafter “Gibbs”). It is noted that Claims 92, 130, 163-204 are not pending in this application. However, Applicants will proceed as though the rejection applies to Claims 232 and 241-255. As restated, these rejection are respectfully traversed for at least the reasons which follow.

(1) Ibrahini: In rejecting the claims at issue, the Examiner asserts that Ibrahini “clearly anticipate the instant compounds of formula (VIII)” *Office Action* mailed July 28, 2009 at page 6. Again, while not agreeing with the rejection, the claims have been amended such that R¹ and R² can no longer be selected from hydrogen. Whatever else Ibrahini may teach or suggest, it does not disclose or suggest compounds overlapping with the specific compounds now recited in Applicants claims. More particularly, Ibrahini does not teach or suggest any structure, formulae or embodied compounds which overlap with the specific definitions recited in the claims for R¹ and R². Ibrahini therefore does not teach each and every element of the present claims. For at least this reason, withdrawal of this rejection is therefore respectfully requested.

(2) Hopper: Again, in rejecting the claims at issue, the Examiner asserts that Hopper disclose five compounds that “clearly anticipate the instant compounds of formula (VIII)” *Office Action* mailed July 28, 2009 at page 6. Again, while not agreeing with the rejection, the claims have been amended such that k can no longer be selected from 0. Whatever else Hopper may teach or suggest, it does not disclose or suggest compounds overlapping with the specific compounds now recited in Applicants claims. Hopper therefore does not teach each and every

element of the present claims. For at least this reason, withdrawal of this rejection is therefore respectfully requested.

(3) Li: In rejecting the claims at issue, the Examiner asserts that Li discloses two compounds that “clearly anticipate the instant compounds of formula (VIII)” *Office Action* mailed July 28, 2009 at page 6. Initially, it is noted that the compounds of Examples 14 and 15 of Li are clearly encompassed within proviso d) of claim 232, and thus not within the scope of the claims. Nonetheless, without agreeing with the rejection, proviso d) has been amended to further exclude limited compounds wherein R^3 is alkyl of 1 to 6 carbons. Whatever else Li may teach or suggest, it does not disclose or suggest compounds overlapping with the specific compounds now recited in Applicants claims. Li therefore does not teach each and every element of the present claims. For at least this reason, withdrawal of this rejection is therefore respectfully requested.

(4) Gibbs: In rejecting the claims at issue, the Examiner asserts that Gibbs disclose two compounds that “clearly anticipate the instant compounds of formula (VIII)” *Office Action* mailed July 28, 2009 at page 7. As described above with reference to Ibrahimi, while not agreeing with the rejection, the claims have been amended such that R^1 and R^2 can no longer be selected from hydrogen. Whatever else Gibbs may teach or suggest, it does not disclose or suggest compounds overlapping with the specific compounds now recited in the Applicants claims. Gibbs therefore does not teach each and every element of the present claims. For at least this reason, withdrawal of this rejection is therefore respectfully requested.

For at least these reasons, withdrawal of these rejections is respectfully requested.

III. Claim Rejections under 35 U.S.C. § 103

A. Rejection over Li

Claims 232 and 241-255 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Li. This rejection is respectfully traversed for at least the reasons which follow.

The Examiner has alleged the compounds of Li overlap with the present invention, but has acknowledged that Li does not disclose the exact scope of compounds claimed by Applicant. See *Office Action* mailed July 28, 2009 at pages 8-9. However, in support of the rejection, the Examiner asserts that the “one would be motivated to employ the compounds/compositions of Li

et al. to obtain the instant compounds of formula (VIII)” and that the “motivation to obtain the claimed compounds/compositions derives from known Li et al. compounds would [sic] possess similar activities (i.e., compositions) to that which is claimed in the reference.” *Office Action* mailed July 28, 2009 at page 9. Based on such generalized assertions, the Examiner concludes that the claimed invention would have been obvious to one of ordinary skill in the art.

Applicants disagree.

The Supreme Court has addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Court stated that the *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), factors still control an obviousness inquiry. Those factors are: 1) “the scope and content of the prior art”; 2) the “differences between the prior art and the claims”; 3) “the level of ordinary skill in the pertinent art”; and 4) objective evidence of nonobviousness. *KSR*, 127 S. Ct. at 1734 (quoting *Graham*, 383 U.S. at 17-18). While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the Court acknowledged the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. *KSR*, 127 S. Ct. at 1731. Moreover, the Court indicated that there is “no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.” *Id.* As long as the test is not applied as a “rigid and mandatory” formula, that test can provide “helpful insight” to an obviousness inquiry. *Id.* In this regard, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning **with some rational underpinning** to support the legal conclusion of obviousness.” *KSR*, 127 S.Ct. at 1741 (quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

The test for *prima facie* obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*. “Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Takeda Chemical Industries, Ltd v. Alphapharm Pty., Ltd.*, 2007 WL 1839698, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007). Further, as the *KSR* Court recognized, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, **predictable** solutions, a

person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 127 S. Ct. at 1732 (emphasis added). In such circumstances, “the fact that a combination was obvious to try might show that it was obvious under § 103.” *Id.*

However, as in *Takeda* where the claimed compound was found non-obvious by the court even though it may have been “obvious to try”, this is not the case here. In *Takeda*, rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Similarly, in the present case, the prior art cited by the Examiner merely suggests a **general approach** that may give rise to a broad selection of **theoretical** compounds, any one of which would have been **unpredictable** in its putative function prior to the present invention.

As stated above, by way of proviso d), the present claims specifically exclude the compounds disclosed in Li. As such, there is no actual overlap between the teachings of Li and the present claims. At most, Li provides a **general approach** to selecting **theoretical** compounds from a broad array of potential compounds -- without any motivation or guidance so as to lead those of skill in the art to conclude that any particular selection would be more predictable over another for the purpose of the present claims. Without any specific guidance that a particular phosphinic acid selection would be a particularly suitable for use with any other particularly suitable selection within the scope of the present claims, Li simply does not render the present claims obvious. The general allegations in the Office Action of compounds that would “possess similar activities” would not lead those of skill in the art to select the particular combinations of substituents and modify the teachings accordingly so as to arrive at the present claims based on the broad possibilities in Li. Such a general approach does not dictate success with predictability.

For at least these reasons, it is respectfully submitted that the claims are patentable over the cited art, and withdrawal of this rejection is respectfully requested.

B. Rejection over Gibbs

Claims 232 and 241-255 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Gibbs. This rejection is respectfully traversed for at least the reasons which follow.

Again, the Examiner has alleged the compounds of Gibbs overlaps with the present invention, but has acknowledged that Gibbs does not disclose the exact scope of compounds

claimed by Applicant. See *Office Action* mailed July 28, 2009 at pages 8-9. However, in support of the rejection, the Examiner asserts that the “one would be motivated to employ the compounds/compositions of Gibbs et al. ‘163 to obtain the instant compounds of formula (VIII)” and that the “motivation to obtain the claimed compounds/compositions derives from known Gibbs et al. compounds would [sic] possess similar activities (i.e., compositions) to that which is claimed in the reference.” *Office Action* mailed July 28, 2009 at page 9. Based on such generalized assertions, the Examiner concludes that the claimed invention would have been obvious to one of ordinary skill in the art. Applicants disagree.

As stated above, by way of the definition of R¹ and R² in the present claims, there is no actual overlap between the teachings of Gibbs and the present claims. At most, Gibbs provides a **general approach** to selecting **theoretical** compounds from a broad array of potential compounds -- without any motivation or guidance so as to lead those of skill in the art to conclude that any particular selection would be more predictable over another for the purpose of the present claims. Without any specific guidance that a particular phosphinic acid selection would be a particularly suitable for use with any other particularly suitable selection within the scope of the present claims, Gibbs simply does not render the present claims obvious.

The general allegations in the Office Action of compounds that would “possess similar activities” would not lead those of skill in the art to select the particular combinations of substituents and modify the teachings accordingly so as to arrive at the present claims based on the broad possibilities in Gibbs. The compounds made by Gibbs are inhibitors of phosphoinositide-specific phospholipase C, while the compounds from the present application are thyroid hormone agonists. There are no teaching in Gibbs that would suggest to those skilled in the art that the compounds described in Gibbs could be ligands for the thyroid hormone receptor. Absent such a teaching, one of skill in the art would have no predictable motivation to select the particular combinations of substituents from the broad possibilities in Gibbs so as to arrive at the present invention. Such a general approach does not dictate success with predictability.

For at least these reasons, it is respectfully submitted that the claims are patentable over the cited art, and withdrawal of this rejection is respectfully requested.

IV. Obviousness Double Patenting Rejection

Claims 232 and 241-255 stand rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1 and 13 of Erion *et al.*, US Pat 7,514,419, and claims 78, 113, and 116 of co-pending Erion *et al.*, U.S. Application Serial No. 11/816,774.

While not agreeing with the rejections, in order to facilitate prosecution, Applicants are willing to submit a Terminal Disclaimer in the present case with regard to US Pat 7,514,419, and/or co-pending application U.S. Application Serial No. 11/816,774, as appropriate, upon an indication of allowable subject matter. As such, it is requested that the obviousness type double patenting rejections be held in abeyance until such time as the claims in the present application are in condition for allowance. It is noted that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. See, *e.g.*, *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991) (“filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.”)

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is encouraged to contact the undersigned at (303) 863-2303 should any additional information be necessary for allowance.

Respectfully submitted,

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